JC10 Rec'd PC TO 19 JUL 2005 PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

in re the Application of: Tetsushi TAGUCHI et al.

Group Art Unit: Not yet assigned

Serial No.: 10/527,694

Examiner: Not yet assigned

Filed: March 11, 2005

Confirmation No.: Not yet assigned

For: BIOLOGICAL LOW-MOLECULAR WEIGHT DERIVATIVES

Attorney Docket Number: 052203

Customer Number: 38834

SUBMISSION OF ENGLISH TRANSLATION OF IPER

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

July 19, 2005

Sir:

Submitted herewith is an English translation of the International Preliminary Examination Report for the above-identified U.S. patent application. Please note that the cited references of the International Preliminary Examination Report were previously filed with the Information Disclosure Statement on March 11, 2005.

If any additional fees are due in connection with this submission, please charge our Deposit Account No. 50-2866.

Respectfully submitted,

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Enclosure: Form PCT/IB/338

From the INTERNAT AL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL OF COPIES OF TRANSLATION OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 72.2)

To:

NISHI, Yoshiyuki Nishi Patent Office Suite 211, 26-32, Nakahara 4-chome Isogo-ku Yokohama-shi, Kanagawa 235-0036 JAPON

Date of mailing (day/month/year) 26 May 2005 (26.05.2005)	
Applicant's or agent's file reference 03-W-19	IMPORTANT NOTIFICATION
International application No. PCT/JP2003/011669	International filing date (day/month/year) 11 September 2003 (11.09.2003)
Applicant NATIONAL IN	ISTITUTE FOR MATERIALS SCIENCE et al

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

CA, CN, EP

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

US

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

Masashi Honda

Facsimile No.+41 22 740 14 35

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Form PCT/IB/338 (July 1996)



Translation

PATENT COOPERATION TREA



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03-W-19	FOR FURTHER A	ACTION	See Form PCT/IPEA/416	
International application No.	International filing d	ate (day/month/year)	Priority date (day/month/year)	
PCT/JP2003/011669	11 September 2	003 (11.09.2003)	11 September 2002 (11.09.2002)	
International Patent Classification (IPC) or n C07D 207/46, C08J 3/24 // A61I	national classification a L 27/18, 26/00	and IPC		
Applicant NATION	AL INSTITUTE F	OR MATERIALS	SCIENCE	
This report is the international preling Authority under Article 35 and trans	ninary examination resmitted to the applicant	port, established by this t according to Article 36	International Preliminary Examining	
2. This REPORT consists of a total of	4 sheet	s, including this cover sl	neet	
3. This report is also accompanied by A				
a. (sent to the applicant and			sheets, as follows:	
sheets of the descr and/or sheets cont Administrative Ins	taining rectifications a	drawings which have be uthorized by this Autho	en amended and are the basis of this report rity (see Rule 70.16 and Section 607 of the	
sheets which supe beyond the disclor Supplemental Box	sure in the internation	ut which this Authority al application as filed, a	considers contain an amendment that goes as indicated in item 4 of Box No. I and the	
	nal Bureau only) a	total of (indicate type	e and number of electronic carrier(s))	
	dicated in the Supple	uning a sequence listing	g and/or tables related thereto, in computer Sequence Listing (see Section 802 of the	
4. This report contains indications relat	ing to the following ite	ems:		
Box No. I Basis of the re	port			
Box No. II Priority				
Box No. III Non-establishn	nent of opinion with re	egard to novelty, inventi	ve step and industrial applicability	
Box No. IV Lack of unity of	of invention			
Box No. V Reasoned state citations and ex	ment under Article 35 xplanations supporting	(2) with regard to novel	ty, inventive step or industrial applicability;	
Box No. VI Certain docume				
Box No. VII Certain defects in the international application				
Box No. VIII Certain observe	ations on the internatio	onal application		
Date of submission of the demand		Date of completion of	this report	
12 April 2004 (12.04.2004)		01 Oc	stober 2004 (01.10.2004)	
Name and mailing address of the IPEA/JP		Authorized officer		
Facsimile No.		Telephone No.		

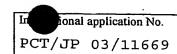
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/011669

DOX 110		basis of the report	
1. With other	regard	to the language, this report is based on the international application in the landicated under this item.	nguage in which it was filed, unless
	This which	report is based on translations from the original language into the following his language of a translation furnished for the purpose of:	ng language,
		international search (under Rules 12.3 and 23.1(b))	
		publication of the international application (under Rule 12.4)	
		international preliminary examination (under Rules 55.2 and/or 55.3)	
		•	
juin	are not	I to the elements of the international application, this report is based on the receiving Office in response to an invitation under Article 14 are referannexed to this report): attenuational application as originally filed/furnished	a (replacement sheets which have been red to in this report as "originally filed"
$\overline{\boxtimes}$		escription:	
	pages	· ·	, as originally filed/furnished
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	pages'	received by this Authority on	, as originally filed/furnished
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	0.000		
لــا	a scqu	ence listing and/or any related table(s) – see Supplemental Box Relating to So	equence Listing.
3.	The ar	nendments have resulted in the cancellation of:	
		the description, pages	
		the claims, Nos 2-3	
	$\overline{\Box}$	the drawings, sheets/figs	
		the sequence listing (specify):	
		any table(s) related to sequence listing (specify):	
	ш ·	and the sequence rising (specify).	•
4.	This re	eport has been established as if (some of) the amendments annexed to this a since they have been considered to go beyond the disclosure as filed, as	report and listed below had not been
	(Rule 7	70.2(c)).	indicated in the Supplemental Box
	۱ ليا	he description, pages	
	t	he claims, Nos.	
		he drawings, sheets/figs	
		he sequence listing (specify):	
		my table(s) related to sequence listing (specify):	
		311 377	
* If item	4 appl	ies, some or all of those sheets may be marked "superseded."	
		1/00 (Por No 1) (I 2004)	

INTERNATIONAL PRELIMINARY EXAMINATION REPORT



V.	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
	citations and explanations supporting such statement

Statement			
Novelty (N)	Claims	4-11	YES
	Claims	1	NO
Inventive step (IS)	Claims	4-11	YES
	Claims	1	NO
Industrial applicability (IA)	Claims	1, 4-11	YES
	Claims		NO

2. Citations and explanations

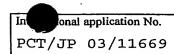
Document 1: JP 61-69759 A
Document 2: WO 01/91814 A

Document 3: Journal of Organic Chemistry, 1996, 61 (24),

pp. 8496-8499

The invention that is set forth in claim 1 lacks novelty in the light of document 3 cited in the international search report. Document 3 presents 2-tertbutyl 1,3-di-N-succinimidyl citrates, and indicates that citrate, which is to say citric acid, is present in the citric acid cycle. Thus, the abovementioned compounds that are presented in document 3 can be said to be citric acid derivatives to which two N-hydroxysuccinimide molecules have been fused by means of condensation; therefore, the compounds in the invention that is set forth in claim 1 are the same as the compounds that are presented in document 3. Meanwhile, in the written response the applicant asserts that "the low-molecular weight biological derivatives that are set forth in claim 1 are limited to 'low-molecular weight biological derivatives characterized in that after application within an organism, the derivatives are hydrolysed and react with biopolymers in the organism.'...Document 3 presents '2-tertbutyl 1,3-di-N-succinimidyl citrates,' but does not make

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any disclosures pertaining to the properties, the applications or the like thereof, and...does not make any disclosures pertaining to the technical characteristics of the invention that is set forth in claim 1..." However, the abovementioned compounds that are presented in document 3 are the same as the compounds in the invention that is set forth in claim 1; therefore, naturally, they must exhibit the property whereby "after application within an organism, the derivatives are hydrolysed and react with biopolymers in the organism."

The inventions that are set forth in claims 4-11 are not disclosed or suggested in documents 1-3 cited in the international search report; therefore, they are novel and involve an inventive step.